

Appl. No. 09/838,382  
Response dated February 24, 2005  
Reply to Final Office Action of November 24, 2004

### REMARKS/ARGUMENTS

1. Claims 3-16 were previously pending. Claims 3-13 were withdrawn from consideration by the Examiner, as being drawn to a non-elected invention. Claims 14 and 15 have been allowed. Claim 16 has been rejected.

Applicants hereby request further examination and reconsideration of the application, in view of the remarks.

2. • Claims 16 has been rejected under 35 U.S.C. 112, first paragraph.

#### ***Rejections of Claim 16 under 35 U.S.C. 112, first paragraph***

3. The Examiner has rejected Claim 16 under 35 U.S.C. 112, first paragraph, "as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

The Examiner states that the written description rejection of Claim 16 "was on the grounds that the written description in this case fails to set forth a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima-1* (ATCC number PTA-4959) as set forth in claim 15" (Page 2; Section 4, Paragraph 1) and that the "function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific

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subject matter later claimed by him or her; **how the specification accomplishes this not material**" (Page 3, Lines 8-11).

The Examiner further asserts, "Applicants' have not shown that they were in possession of a variant strain of *Elmeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959)" (Page 3, Lines 17-20); "an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of the invention" (Page 4, Lines 3-5); "Applicants' have not even pointed to support for the variant strain of claim 16" (Page 4, Lines 19-20); "Possession may be shown in a variety of ways including description of an actual reduction to practice, ... or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Page 5, Lines 3-7); "functional limitations alone are not sufficient to satisfy the written description requirement" (Page 5, Lines 10-12); and "A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process as is the case here... one of skill in the art could not immediately envision the claimed variant strain" (Page 5, Lines 13-15).

The Examiner concludes, "it appears that the instant case sets forth an undisclosed variant strain and asserts that this undisclosed strain has some functional limitations. However, there is no actual disclosure of the claimed variant strain. Moreover, the functional limitations do not constitute a written description of every species in a genus because it would not 'reasonably lead' those skilled in the art to any particular species" (Page 6, Lines 12-17).

Applicant respectfully traverses the rejection. A variant strain of parasite cannot be described by nucleic acid structure. Cell lines, and here a parasitic strain, are described

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by their existence and by their identifying characteristics and not by their DNA sequence.

The instant specification discloses that "[T]he invention includes the immunovariant strain *E. maxima*-I, exemplified in Examples 3-6, individually and its use in vaccinating chickens against a coccidial infection. In a preferred embodiment, the present invention encompasses any strains that correspond in characteristics to the line *E. maxima*-I and other strains derived according to the immunological selection method of the invention. The invention includes such sub-lines of the above strain (having been derived from the same parent) or descendants therefrom (having been derived from the deposited lines by further passaging). The immunovariant strain of the invention can be used individually or in any combination of the strain of the invention with one or more other live or attenuated *Eimeria* organisms, in any proportions. The invention further includes feed or drink, including water, containing parasites of the line" (Page 9, Lines 7-17). The instant specification further discloses other immunovariants having the same characteristics as strain *E. maxima* -I, e.g., in Example 3, *In vivo* Selection of the Immunovariant Strain *E. maxima* -I): "[B]irds immunized by oral infection with the Guelph strain of *E. maxima* (*E. maxima*-GLP) were challenged with the Florida strain. The resulting oocysts were sporulated and then passaged through additional birds immunized against the Guelph strain. Four such passage collections, **using oocysts collected from each preceding passage, were used to challenge the next group of immunized birds and selected for a strain of *E. maxima*, designated *E. maxima* -I, that was totally immunovariant from the *E. maxima*-GPL.** Birds immunized against the Guelph strain no longer recognized the resulting immunovariant *E. maxima* strain, *E. maxima* -I" (Page 14, Lines 15-22). Oocysts having the same identifying characteristics as strain *E. maxima* -I are present in the passage collections disclosed in

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Example 3. As can be seen from the numbers of oocysts disclosed in Table 1, the procedure will generate immunovariant strains having the same identifying characteristics as strain *E. maxima* -I. The instant specification discloses that immunovariant strains exist and that the selection process will yield immunovariant strains as shown in Example 3, Table 1, and the disclosure, "Table 1 shows that *E. maxima* -GPL-immunized birds shed as many oocysts after challenge with the *E. maxima* -I strain as did the non-immunized birds challenged with *E. maxima* -I, indicating no cross-protection. In contrast, the *E. maxima*- GPL- and *E. maxima* -I - immunized birds shed zero or very few oocysts after homologous challenge" (Page 16, Lines 1-5).

Claim 15 recites the distinguishing characteristics by which the variants are distinctly recognizable or known, *i.e.*, those characteristics which are commonly shared by *E. maxima*-I and the variant. Claim 15 recites, "[T]he variant strain *E. maxima*-I (ATCC number PTA-4959) of Claim 14 which is further identified by the characteristic wherein: immunization with *E. maxima*-I (ATCC number PTA-4959) protects against challenge with *E. maxima*-I (ATCC number PTA-4959) but does not protect against challenge with the Guelph strain of *E. maxima*, designated *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-GLP. Claim 16 recites, "A variant strain of *Eimeria maxima* wherein said variant strain corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in Claim 15 wherein: immunization with said variant strain or *E. maxima*-I (ATCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable

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Immunological cross reactivity with *E. maxima*-GLP.

Thus, the specification teaches that variant strains of *Eimeria maxima* wherein said variant strain corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) exist, Claim 15 recites the distinguishing characteristics by which the variants are distinctly recognizable or known, *i.e.*, those characteristics which are commonly shared by *E. maxima*-I and the variant, and Claim 16 recites said variants, the variant strains of *Eimeria maxima* wherein said variant strain corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959).

According to the MPEP (2163.04), a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. The inquiry into whether the description requirement is met must be determined on a case-by-case basis. The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

Applicant contends, as discussed *supra*, that there is support for the claimed invention in the specification and that, therefore, a person skilled in the art would recognize a description of the invention as defined by Claim 16. Applicant respectfully submits that the Examiner has not met the burden.

In view of the above remarks, it is respectfully requested that the rejection under 35 U.S.C. paragraph 112, first paragraph, written description, be withdrawn.

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4. The Examiner has rejected Claim 16 under 35 U.S.C. 112, first paragraph, "as failing to comply with the written description requirement. This is a new matter rejection." The Examiner asserts that the "issue of a lack of adequate written description and new matter may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention" (Page 7, Lines 8-11). The Examiner states that "it is noted that the examples and original claims fail to disclose the identity of a variant strain that is not the deposited strain ATCC PTA-4959 having the claimed characteristics. Therefore, it appears that there is no support in the specification or original claims" (Paragraph bridging Pages 8 and 9).

Applicant respectfully traverses the rejection. No new matter has been introduced by Claim 16. Applicant contends that claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that the Applicant had possession of the claimed invention and has particularly pointed, *supra*, to support in the specification for the claimed invention. As stated above, according to the MPEP (2163.04), a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Applicant respectfully submits that the Examiner has not met the burden.

In view of the above remarks, it is respectfully requested that the rejection under 35 U.S.C. paragraph 112, first paragraph, written description, new matter, be withdrawn.

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### CONCLUSION

The office action was mailed on November 24, 2004, and this response is submitted within the three month period for reply, therefore no extension of time is required and no fee is due. Please charge any additional fees which may be required at any time during prosecution of the instant application to deposit account 50-2134.

Applicants appreciate the Examiner's allowance of Claims 14 and 15. It is believed that all of the claims and the specification are in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and that the instant application be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

February 24, 2005 Evelyn M. Rabin  
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